

REMARKS

Pursuant to the entry of the instant amendment, claims 1, 16, and 18-23 are canceled and claims 2, 4-15, 17, and 24 are amended, leaving at issue claims 2, 4-15, 17, and 24. At the outset, Applicants wish to thank Examiner Tsay for taking the time to discuss the pending rejections and the proposed response with Applicant's representative. Applicants submit that the instant remarks not only address the grounds of rejection set forth in the outstanding Final Rejection of March 12, 2009 but also reflect suggestions presented in the telephonic interview of June 25, 2009.

In particular, in an effort to expedite prosecution, Applicants herewith have amended the sole remaining independent claim – claim 2 – to utilize the closed language (“*consisting of*”) as opposed to the previously iterated open language (“*comprising*”). Applicants have further amended claim 2 to include the limitations of now cancelled dependent claims 16 (i.e., further treating the composition obtained step (ii) to yield at least one purified coagulation factor) and 22 (i.e., performing steps (i) and (ii) at a temperature that ranges from 20°C to 25 °C). Applicants respectfully submit that these amendments render moot the outstanding claim rejections and place the present application in condition for allowance. Further to this position, Applicants submit the following remarks:

Claim Rejections under 35 U.S.C. § 103

In the outstanding Final Office Action, the Examiner finally rejected claims 1, 3-5, and 10-11 under 35 U.S.C. § 103(a) as being obvious over Zykova et al. Applicants note that neither claim 2 nor claim 16 nor claim 22 was included in this rejection. Accordingly, this rejection is rendered moot by the cancellation of independent claim 1.

The Examiner further rejected claims 1-24 under 35 U.S.C. § 103(a) as being obvious over Wallace et al., alone (claims 1-14, 16, and 18-24) or in combination with Burnouf Radosevich et al. (claims 15 and 17). Applicants respectfully submit that the above noted amendments to independent claim 2 serve to distinguish the inventive process from that of Wallace, alone or as modified by Burnouf Radosevich. In particular, Applicants respectfully submit that the closed language of claim 2 precludes the application of the Wallace reference, which describes a complex, multi-step process that includes several distinct steps in addition to

those recited in claim 2 as amended herewith, including multiple centrifugation steps to obtain a purified fibronectin substitute precipitate and further cooling steps to precipitate remaining fibronectin, though capturing at most 60% of the fibronectin present in the original plasma fraction. In contrast, the pending claims relate to a simple, one-step titration process that results in the direct quantitative separation of fibronectin from a plasma solution to yield a purified coagulation factor, more particularly a von Willebrand factor (vWF), as well as the high yield recovery of 70 to 99%, more preferably at least 90% of the fibronectin present in the plasma fraction.

In addition, the Wallace method requires the preparation of fibronectin and fibronectin substitutes from an “acid-chill precipitate”, at temperatures ranging from 2.5 to 7.5 °C. In contrast, the steps of the inventive process are performed at room temperature, i.e., at temperatures ranging from 20°C to 25 °C.

By omitting steps and parameters required by Wallace et al., Applicants are able to obtain significantly improved fibronectin precipitation. To that end, Applicants direct the Examiner’s attention to Example 1 of the instant specification and in particular the data presented in Table 2 which clearly demonstrates that fibronectin removal is most efficient at 20°C, as compared to 4°C (i.e., Wallace et al.) and 35°C. Applicants respectfully submit that the unexpected superior results obtained by Applicants could not have been predicted by one of ordinary skill in the art, particularly in view of the teachings of Wallace et al. that clearly suggest towards acid-chill procedures, and thus serve as further indicia of non-obviousness.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection of claims 1-24 as being obvious over the prior art of record in view of the amendments and remarks presented herewith.

CONCLUSION

In view of the above, Applicant respectfully submits that claims 2, 4-15, 17, and 24 are in condition for allowance and respectfully request an early notification of such.

The outstanding Final Office Action set a three-month shortened statutory period for response. Applicants submit herewith a Petition for a One-Month Extension of Time, extending the deadline for response to on or before **July 13, 2009** (July 12th being a Sunday). Thus, Applicants submits that this response is timely and no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned's Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, he is invited to contact the undersigned.

Respectfully submitted,

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By: **/chalin a. smith/**

Smith Patent Consulting, LLC
3307 Duke Street
Alexandria, VA 22314
Telephone: (703) 549-7691
Facsimile: (703) 549-7692

Name: Chalin A. Smith
Title: Attorney for Applicant
Registration No. 41,569

CUSTOMER NUMBER 31,496